

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD.,

Plaintiff,

v.

SAREPTA THERAPEUTICS, INC.,

Defendant.

SAREPTA THERAPEUTICS, INC. and THE
UNIVERSITY OF WESTERN AUSTRALIA,

Defendant/Counter-Plaintiffs,

v.

NIPPON SHINYAKU CO., LTD.
and NS PHARMA, INC.

Plaintiff/Counter-Defendants.

C.A. No. 21-1015 (JLH)

PUBLIC VERSION

Confidential Version Filed: September 30, 2024

Public Version Filed: October 7, 2024

**SAREPTA'S OPPOSITION TO NS'S MOTION FOR LEAVE TO FILE
MOTION FOR SUMMARY JUDGMENT**

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September 30, 2024

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Dear Judge Hall:

NS's motion for leave to move for summary judgment of invalidity of claim 1 of U.S. Patent No. 9,994,851 ("the Wilton Patent") (D.I. 604)—which is nothing more than a rehash of its prior, already-denied summary judgment motion, only on a significantly worse record for NS—should be denied for a multitude of reasons.

As a threshold matter, NS's motion disregards the Court's three-page letter limit by attaching and effectively incorporating a full-throated summary judgment brief and hundreds of pages of other materials, without even consulting Sarepta or the Court. Moreover, NS's motion is essentially a request for reconsideration of its previously-denied motion—which NS does not even mention, much less attempt to distinguish. As with its prior motion, NS premises its arguments on the purportedly "vast" scope of claim 1. Not only did the Court deny that motion, but things got significantly worse for NS after that, when the Court ruled that claim 1 requires "100% complementarity" between the claimed antisense oligonucleotide (ASO) and its target, thus **narrowing** the scope of the claim—so much so that NS was unprepared to proceed to trial and asked for several months to regroup. D.I. 573. This development was fatal to NS's position. After all, if summary judgment for written description and enablement was improper under a broad reading of claim 1—as the Court already found—it is *ipso facto* improper under a narrower reading. Finally, NS's motion is premised on a series of hotly disputed material facts, any one of which is fatal to NS's cause. Relitigating NS's proposed summary judgment would be a waste of the Court's and the parties' time and resources.

I. NS's Motion Violates the Court's Order and Local Rules

NS's letter itself may only be a single page, but it includes more than **four hundred pages** of attachments, including a proposed motion for summary judgment (Ex. A), a sixteen-page memorandum (Ex. A-1), a six-page statement of allegedly undisputed facts that supposedly form the basis for its motion to leave (yet are not included in the letter itself) (Ex. A-2), and hundreds of pages of exhibits. The voluminous nature of NS's submission alone betrays its position that the issues are simple or undisputed. It also contravenes the Court's Order that a party "may file a **three-page** letter seeking leave to file summary judgment." D.I. 597 (emphasis added). If litigants were allowed to contravene this rule by attaching voluminous materials setting forth their arguments and evidence, the three-page limit would be meaningless. NS also violated the Court's Local Rules by failing to meet and confer with Sarepta prior to filing its motion. *See* D. Del. LR 7.1.1. NS's motion should be denied for these reasons alone.

II. NS's Motion Is Meritless

A. NS's Proposed Motion for Summary Judgment Raises the Same Arguments Previously Rejected by This Court

NS's motion should also be denied because it seeks to relitigate issues that were already considered and rejected by the Court. NS previously moved for summary judgment on written description and enablement grounds, alleging that claim 1 "broadly encompass[es] at least many tens of thousands (if not many trillions) of candidate A[S]Os" and that the "unpredictability" in the art "necessitates extensive trial-and-error experimentation." *See generally* D.I. 400. The Court denied NS's motion in view of "genuine disputes of material facts" central to both grounds, including whether the specification "conveys to a POSA that the inventors had possession of the claimed subject matter as of the filing date" and "whether the specification teaches a POSA how

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to make and use the full scope of the claimed invention without undue experimentation.” D.I. 549.

Despite the Court’s amended claim construction substantially narrowing the scope of the Wilton Patent’s claimed genus (D.I. 573) and despite the Court’s Order that a moving party must focus on “an issue affected by the supplemental expert reports” (D.I. 597), NS seeks to burden the Court with the *same arguments* it raised before unsuccessfully—in many instances literally cut and pasted from NS’s prior, ill-fated brief.

NS’s Prior Motion (D.I. 400)	NS’s Proposed Motion (Ex. A-1)
“The UWA Patents’ broadly claimed genus casts <i>a very wide net</i> potentially encompassing at least <i>tens of thousands</i> , if not millions or trillions, of candidate A[S]Os, including NS’s VILTESPO [<i>sic</i>].”	“Claim 1’s broad genus casts <i>a very wide net</i> encompassing at least <i>tens of thousands</i> , if not billions, of candidate A[S]Os, including NS’s VILTESPO [<i>sic</i>].”
“Sarepta’s <i>purported ‘hot spot’</i> cannot establish any structure-function correlation for the A[S]Os falling within the claimed genus”	“[T]he <i>purported ‘hot spot’</i> cannot establish any structure-function correlation for the A[S]Os falling within the claimed genus.”
“the field of exon skipping is <i>highly unpredictable</i> further necessitating a robust disclosure to satisfy the written description requirements”	“the field of exon skipping is <i>highly unpredictable</i> , further necessitating a robust disclosure to satisfy the written description requirements”

In addition to rehashing the same disputed facts, NS’s proposed motion for summary judgment also relies on essentially the *same cases* cited in its prior motion, including *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023), *Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019), and *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021). See Ex. A-1, 8-9, 16. As previously explained, however, these cases involved substantially different technologies (e.g., antibodies as opposed to ASOs), procedural postures (e.g., decided after a jury trial rather than on summary judgment), and disclosures (e.g., patents that lacked the robust structure-function correlation disclosed in the Wilton Patent). See D.I. 469, 11-13, 22-24. These cases were and are inapposite.

To the extent NS argues that its proposed motion raises new arguments that its prior motion did not raise, that argument is unavailing. NS could have raised any of its “new” arguments before. That those arguments did not even make the cut the first time around is a reason to deny, not grant, NS’s motion for leave to file.

B. NS’s Proposed Motion Highlights Genuine Disputes of Material Facts

NS’s motion should also be denied because of the multitude of material facts in dispute. NS’s letter argues that the scope of claim 1 is very large. D.I. 604, 1. Sarepta disputes this. NS’s letter argues that the Wilton Patent fails to disclose a structure-function correlation. *Id.* Sarepta also disputes this. Without any analysis of predictability or the relevant factors, NS contends that there are no factual disputes regarding enablement. *Id.* Sarepta again disputes this. To illustrate the fundamental nature of these disputes, the table below contrasts just a few of the many exemplary facts that NS purports are undisputed versus Sarepta’s evidence to the contrary. Any of these disputed facts alone would be sufficient to defeat NS’s proposed motion for summary judgment.

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NS's Purported Undisputed Facts	Evidence in the Record
<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED], Ex. 2 (Hastings Suppl.) ¶70, and [REDACTED]</p> <p>[REDACTED], <i>id.</i> ¶72.</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>Ex. 3 (Dr. Dowdy), ¶¶49, 53, 133-134, 166.</p>
<p>18. The specification does not use the term “hot spot,” “hotspot” or “hot-spot,” <i>nor does it state that the region delineated by positions +23+69 in the human exon 53 pre-mRNA is a region amenable to exon skipping.</i> See D.I. 2-9, Ex. I (’851 Patent); <i>see also</i> Ex. 6 (Dowdy Suppl. Dep.) 355:3-11.</p>	<p>[REDACTED]</p> <p>Ex. 3 (Dr. Dowdy), ¶62.</p> <p>[REDACTED]</p> <p>[REDACTED]</p> <p>D.I. 471-4, Ex. 12 ([REDACTED]), SRPT-VYDS-0201529-30.</p>
<p>[REDACTED]</p>	<p>[REDACTED]</p> <p>[REDACTED]</p> <p>D.I. 471-2, Ex. 7 (Dr. Wilton), 55:4-10.</p>

NS’s motion for leave to file a summary judgment motion, which disregards the extent and degree of disputes between the parties’ experts on numerous material facts, should be denied.

III. Conclusion

Ten months ago, NS failed to satisfy the standard for summary judgment in seeking to invalidate the Wilton Patent on written description and enablement grounds. Today, NS is farther away from meeting that standard, as the claim scope is indisputably narrower, and the evidence is very much in dispute. Granting NS’s motion for leave, filed in violation of both the Court’s Order and the Local Rules, would waste the Court’s and the parties’ time and resources. Sarepta respectfully requests that the Court deny NS’s motion for leave to file a summary judgment motion, and that the case proceed to trial.

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Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac

cc: Clerk of the Court (via hand delivery)
All Counsel of Record (via electronic mail)